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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/527,460

03/11/2005

Josef Beden

P70415US0

2533

136 7590 06/11/2007

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EXAMINER

DEAK, LESLIE R

ART UNIT

PAPER NUMBER

3761

MAIL DATE

DELIVERY MODE

06/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/527,460

Applicant(s)

BEDEN ET AL.

Examiner

Leslie R. Deak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 May 0311 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12/21/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 4, 8, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over A1 US 6,132,616 to Twardowski et al in view of DE 42 40 681 to Polaschegg.

In the specification and figures, Twardowski discloses the method substantially as claimed by applicant. With regard to claim 1, Twardowski discloses a method for return of blood from a treatment apparatus. The apparatus comprises a dialyzer 100, two lines 144, 146, with outlets 145a, 145b, blood pump 148, first valve 168 in the first line, second valve 174 in the second line line/port 166 for feeding of substitute fluid 164 in a predilution location. Twardowski discloses that after the completion of blood treatment, first valve 168 is opened to connect saline bag exclusively to the blood line, indicating that valve 174 is closed. Saline moves into inlet line 144, pushing blood out of the system (including blood pump 148) back to the patient. Then valve 168 closes and

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saline is pushed through the outlet line 146, returning blood to the patient (see column 14, lines 39-60).

Twardowski fails to disclose the presence and use of a substitute pump to move the substitute fluid through the circuit. Polaschegg discloses and illustrates a dialysis apparatus with a substitute fluid 46 connected via line 44 and pump 50 to blood path 36. The pump is used to move fluid through the blood path at various points in the procedure (see abstract).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add and use the substitute pump disclosed by Polaschegg to the apparatus and method disclosed by Twardowski in order to more accurately control the movement of substitute fluid through the circuit, as suggested by Polaschegg.

4. Claims 2 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over A1 US 6,132,616 to Twardowski et al in view of in view of US 5,470,483 to Bene et al.

In the specification and figures, Twardowski discloses the method substantially as claimed by applicant. With regard to claim 1, Twardowski discloses a method for return of blood from a treatment apparatus. The apparatus comprises a dialyzer 100, two lines 144, 146, with outlets 145a, 145b, blood pump 148, first valve 168 in the first line, second valve 174 in the second line line/port 166 for feeding of substitute fluid 164 in a predilution location. Twardowski discloses that after the completion of blood treatment, first valve 168 is opened to connect saline bag exclusively to the blood line, indicating that valve 174 is closed. Saline moves into inlet line 144, pushing blood back

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to the patient. Then valve 168 closes and saline is pushed through the outlet line 146, returning blood to the patient (see column 14, lines 39-60).

Twardowski fails to disclose the presence and use of a substitute pump to move the substitute fluid through the circuit in a postdilution location. Bene discloses and illustrates a dialysis apparatus with a substitute fluid 10 connected via line and pump 10 to blood path 7 in a postdilution location. The pump is used to move fluid through the blood path at various points in the procedure (see column 2, lines 30-49).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add and use the substitute pump disclosed by Bene in a postdilution location to the apparatus and method disclosed by Twardowski in order to more accurately control the movement of substitute fluid through the circuit, as suggested by Bene.

With regard to claim 5, Bene discloses that exchanger 2 is suitable for ultrafiltration of blood, meeting the limitations of the claim (see column 2, lines 30-49).

5. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over A1 US 6,132,616 to Twardowski et al in view of DE 42 40 681 to Polaschegg, further in view of US 4,770,769 to Schael.

In the specification and figures, the prior art suggest the apparatus and method substantially as claimed by applicant with the exception of a membrane pump as the substitute pump. Schael discloses a hemodialysis apparatus that uses membrane pumps in the device in order to accurately control the operation of the system in response to system and patient parameters (see column 6, line 50 to column 7, line 5).

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Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to substitute a membrane pump as disclosed by Schael for the pumps in the system suggested by Twardowski and Polaschegg in order to provide accurate pumping control, as taught by Schael.

6. Claims 6, 7, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over A1 US 6,132,616 to Twardowski et al in view of DE 42 40 681 to Polaschegg, further in view of US 5,783,072 to Kenley et al.

In the specification and figures, the prior art suggest the apparatus and method substantially as claimed by applicant (including parallel pumps, see Polaschegg) with the exception of using optical sensors to detect the presence of substitute fluid rather than blood in the tubing lines. Kenley discloses a method and apparatus for blood filtration that uses optical sensors 446, 486 in arterial and venous lines 432, 492 to sense the concentration of blood in the lines. When the concentration has reached a certain level, indicating that the substitute fluid is flowing through the lines, the rinseback is stopped to prevent excess fluid return to the patient (see column 48, lines 17-55). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to add optical sensors as disclosed by Kenley to the apparatus and method suggested by the prior art in order to monitor fluid return and prevent excess fluid from returning to the patient, as taught by Kenley.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

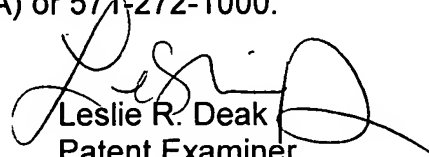
- a. US 2006/0254982 Kopperschmidt
 - i. Process and device for monitoring substitute fluid during extracorporeal treatment of blood
- b. US 2006/0237351 Felding
 - ii. Method of operating a dialysis machine incorporating saline replacement fluid with pump

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Leslie R. Deak
Patent Examiner
Art Unit 3761
7 June 2007